Producers of Quality
Nonprescription Medicines and Dietary Supplements for Self-Care

CONSUMER HEALTHCARE PRODUCTS ASSOCIATION
Formerly Nonprescription Drug Manufacturers Association

October 22, 1999

Charles Ganley, M.D.
Director, Division of OTC Drug Products
HFD 560, Room 5205
Food and Drug Administration
5600 Fishers Lane
Rockville, MD 20857

Re: Docket No.: 96N-0420, 92N-454A, 90P-0201, and 95N-0259

Dear Dr. Ganley:

We received your letter about rescheduling the November 1st feedback meeting on OTC label content and format. This is a disappointment to our group, as we have been working diligently to develop the appropriate mock-ups that would compliment the meeting materials that we sent to you on October 15th.

We urge you to reconsider the November 1st meeting date. The OTC Final Rule on Labeling is easily the most important rule and activity affecting the OTC arena. We firmly believe that, with cooperative interaction between our groups between now and November 1st, as suggested in my October 1st letter to you, we can have a productive meeting. On this point, MaPP 4512.1 on meetings between FDA and external constituencies states that "...the meeting may take place if the [CDER] component believes it would still be useful, even with a shorter time to review the package."

However, should you decide to hold to the rescheduled November 23rd date, then we would certainly anticipate well in advance of the meeting an answer from FDA on the three issues which remain outstanding: use of columns, trade dress, and our Citizen Petition for a time extension. The matters of columns and trade dress have lingered too long, and a response from FDA is urgently needed by our members. Presumably, a rescheduled date will help enable FDA to develop the needed responses on these items.

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Importantly, we would like to hand deliver the materials for the next feedback meeting. Either we can do that very early next week, should the meeting occur on November 1st, or we can do that on November 2nd. Would it be possible to meet with even a portion of the FDA team to walk through the mock-ups? Having had extensive experience in the labeling area, our group of Label Coordinators believes a short, informal, non-policy, information-transfer meeting would be very advantageous in helping to speed along the process. We'd appreciate an early answer on this.

In addition, we note that you have changed the amount of time for receipt of materials prior to the feedback meetings from two weeks to three weeks. We note in MaPP 4512.1 pertaining to meetings between CDER and external constituencies and under the Draft Guidance for Industry for Formal Meetings with Sponsors and Applicants for PDUFA Products (re: Meetings A and C), "at least two weeks" is the time period specified for sharing materials prior to a meeting. At the September 17th feedback meeting, you mentioned two weeks as the time period for sharing materials prior to the feedback meetings. Why is the Division now appearing to change CDER policy concerning the time period for sharing materials prior to meetings? Here, too, we look for an early reply. Thanks.

Sincerely yours,

R. William Soller, Ph.D.

R. William Soller, Ph.D.
Senior Vice President and
Director of Science & Technology

cc: R. DeLap, M.D.
M. Lumpkin, M.D.
CHPA Label Coordinators
CTFA

WS/jkq:I/Labeling/GanlNovResp

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FAX TRANSMISSION

DATE: 10/22/99

TO: Dockets Management Branch

FROM: DR Bill Sollek

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MESSAGE: see attached

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CROSS REFERENCE SHEET

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